

TOPCARE CHILDRENS ALL DAY ALLERGY- cetirizine hcl solution
Topco Associates LLC

Topco Associates LLC. Children's All-Day Allergy Drug Facts

Active ingredient (in each 5 mL)

Cetirizine HCl 5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use

if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have

liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are

taking tranquilizers or sedatives.

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- use only with enclosed dosing cup
- find right dose on chart below
- mL = milliliter

adults and children 6 years and over	5 mL or 10 mL once daily depending upon severity of symptoms; do not take more than 10 mL in 24 hours.
adults 65 years and over	5 mL once daily; do not take more than 5 mL in 24 hours.
children 2 to under 6 years of age	2.5 mL once daily. If needed, dose can be increased to a maximum of 5 mL once daily or 2.5 mL every 12 hours. Do not give more than 5 mL in 24 hours.
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- store between 20° to 25°C (68° to 77°F)
- **do not use if carton is opened, or if printed neckband is broken or missing**
- see bottom panel for lot number and expiration date

Inactive ingredients

anhydrous citric acid, artificial grape flavor, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucralose

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

COMPARE TO CHILDREN'S ZYRTEC® ACTIVE INGREDIENT

children's All-Day Allergy

CETIRIZINE HYDROCHLORIDE ORAL SOLUTION 1 mg/mL

ANTIHISTAMINE

INDOOR & OUTDOOR ALLERGIES

24 HOUR

RELIEF OF:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

Dye Free & Sugar Free

2 years & older

GRAPE FLAVOR

4 FL OZ (118 mL)

Dosing cup included



TOPCARE CHILDRENS ALL DAY ALLERGY

cetirizine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-475
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)			CETIRIZINE HYDROCHLORIDE	5 mg in 5 mL
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SORBITOL SOLUTION (UNII: 8KW3E207O2)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color			Score	
Shape			Size	
Flavor		GRAPE	Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-475-26	1 in 1 CARTON	02/02/2016	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-475-00	1 in 1 CARTON	11/01/2021	
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA204226	02/02/2016	

Labeler - Topco Associates LLC (006935977)